510(K) SUMMARY

Submitter Information

Submitter's Name: Design Standards Corporation
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Date Prepared: May 19, 2014

Device Trade Name: Flex™ Endoscopic Instruments

Classification: Class 2

Product Code(s): GCJ, GEI, GEX

Regulation Number(s): 21 CFR 876.1500 Endoscope and Accessories

Predicate Device: Covidien SILS™ and Endoscopic Hand Instruments (K091869, K951589, K914752)
Microsurge, Inc. Endoscopic Laser Fiber Holder (K912332)
United States Surgical Corporation, Endoscopic Needle Driver (K933725)

Intended Use:

The Flex™ Monopolar Maryland Dissector is a single use electrosurgical device intended to be used in conjunction with an electrosurgical generator with applications in endoscopic surgical procedures to facilitate cutting, coagulating, dissection, and manipulation of tissue.

The Flex™ Monopolar Needle Knife is a single use electrosurgical device intended to be used in conjunction with an electrosurgical generator with applications in endoscopic surgical procedures to facilitate cutting, coagulating, dissection, and manipulation of tissue.

The Flex™ Monopolar Spatula is a single use electrosurgical device intended to be used in conjunction with an electrosurgical generator with applications in endoscopic surgical procedures to facilitate cutting, coagulating, dissection, and manipulation of tissue.

The Flex™ Needle Driver is a single use endoscopic device with applications in endoscopic surgical procedures to facilitate dissection and manipulation of tissue.

The Flex™ Fenestrated Grasper is a single use endoscopic device with applications in endoscopic surgical procedures to facilitate dissection and manipulation of tissue.

The Flex™ Monopolar Scissor is a single use electrosurgical device intended to be used in conjunction with an electrosurgical generator with applications in endoscopic surgical procedures to facilitate cutting of tissue.

The Flex™ Laser Fiber Holder is a single use endoscopic device with applications in endoscopic surgical procedures to house and introduce a laser fiber.

Device Description/Technological Characteristics:

The Flex™ Instruments are endoscopic instruments used for endoscopic minimally invasive surgical procedures to manipulate dissect, and cut tissue. Devices are either monopolar endoscopic instruments for tissue manipulation and cutting/coagulation, or non-powered endoscopic instruments for tissue manipulation dissection, and cutting. The instrument shafts have a rigid proximal section and flexible steerable distal "end effector" section. The flexible shaft section and end effector tip have a maximum diameter of 4mm.The steerable function provides 5 degrees of freedom. There are seven different instrument types. Four of the instruments are monopolar electrosurgical devices for cutting and coagulation of tissue. The seven instruments are identified as follows

Flex™ Endoscopic Instruments		
Name	Catalog/REF #	Monopolar Electrosurgical Yes or No
Flex™ Monopolar Maryland Dissector	FXG0350D	Yes
Flex™ Monopolar Needle Knife	FXK0350M	Yes
Flex™ Monopolar Spatula	FXE0350M	Yes
Flex™ Needle Driver	FXN0350S	No
Flex™ Fenestrated Grasper	FXG0350F	No
Flex™ Monopolar Scissor	FXS0350M	Yes
Flex™ Laser Fiber Holder	FXL0350U	No

Performance Data:

Bench testing of the Flex™ Monopolar instruments was performed to evaluate device function and durability. Mechanical testing and simulated use testing was conducted to confirm that the device has the necessary mechanical performance for its intended use.

Dimensional verification was performed to confirm that the device dimensions are as specified.

Electrical safety and Electromagnetic Compatibility testing was conducted in accordance with:

IEC 60601-1: 2005 3d Edition: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2007, Medical Electrical Equipment -Part 1-2: General Requirements for Safety Collateral Standard Electromagnetic Compatibility Requirements and Tests.

IEC 60601-2-2:2009, 5th Edition, Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment

Biocompatibility testing was conducted according to the following ISO Standards:

ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro Cytotoxicity.

ISISO 10993-10:2002 (Al :2006), Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

ISO 10993-11:2006, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

Test results of all nonclinical testing were acceptable and demonstrate that the device is safe and effective for its intended use.

Substantial Equivalence:

Flex™ Endoscopic Surgical Instruments and the predicate devices identified above have the same intended use and similar indications, technological characteristics, and principals of operation. A comparison chart is provided to illustrate substantial equivalence.

Substantial Equivalence Comparison Chart					
Feature/ Specification	**Flex™ Instruments**	**Covidien SILS and Endoscopic Instruments**	**Microsurge Laser Fiber Holder**	**United States Surgical Corporation Endoscopic Needle Driver**	**Comparison**
Regulatory Clearance/ Approval Reference	NA	K091869, K951589, K914752	K912332	933725	NA
Product Code	GCJ, GEI	GCJ, GEI	GEX	GCJ	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.4810	21 CFR 876.1500	Same
Regulation Name	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories	Same

Substantial Equivalence Comparison Chart					
Feature/ Specification	**Flex™ Instruments**	**Covidien SILS and Endoscopic Instruments**	**Microsurge Laser Fiber Holder**	**United States Surgical Corporation Endoscopic Needle Driver**	**Comparison**
Where used (environment)	Endoscopic surgical procedures	Endoscopic surgical procedures	Endoscopic surgical procedures	Endoscopic surgical procedures	Same
Handle design	Pistol Grip or Wand	Pistol Grip	Wand	Pistol Grip	Same
Articulating Feature	Yes, ~90°	Yes, ~80°	No	No	Similar with only minor differences in the articulation range
Tip rotation	Yes, 360°	Yes, 360°	NA	Yes	Same
Manual Operation for rotation and articulation	Yes	Yes	NA	NA	Same
Instrument types	Graspers, dissectors, scissors, needle knife, needle holder, laser fiber holder	Graspers, dissectors, scissors, L-hook knife	Laser Fiber Holder	Endoscopic Needle Driver	Similar, the needle knife function is similar to the L-Hook, the laser holder has similar design to the needle knife but is not an electrosurgical device and simply holds the laser fiber for safe introduction. The needle holder is similar to the graspers and dissector but is not an electrosurgical device. These differences do not introduce new concerns

Substantial Equivalence Comparison Chart					
Feature/ Specification	**Flex™ Instruments**	**Covidien SILS and Endoscopic Instruments**	**Microsurge Laser Fiber Holder**	**United States Surgical Corporation Endoscopic Needle Driver**	**Comparison**
					regarding safety and performance.
Device locking features to hold articulation position	Yes	Yes	NA	NA	Same
Minimum endoscopic cannula size	4 mm minimum	5 mm	Unknown	Unknown	Same
Electrosurgical Function	Yes, monopolar	Yes, monopolar	NA	NA	Same
Insertable shaft length	54 cm (rigid plus flexible)	36 ad 46 cm	Unknown	Unknown	Minor difference in insertion length. These differences do not introduce new concerns regarding safety and performance.
Shaft Diameter	3.5 mm flexible section 8 mm rigid section	Various from ~5-15 mm	Unknown	Unknown	Similar, the range for the Flex™ instruments is more or less within the range for the predicate device.
Shaft flexibility	Flexible throughout 31 cm length	Flexible at shaft tip	NA	NA	Similar, both have flexible shaft portions. The Flex™ design can accommodate a shaped or flexible cannula in addition to a rigid straight cannula.

Substantial Equivalence Comparison Chart					
Feature/ Specification	**Flex™ Instruments**	**Covidien SILS and Endoscopic Instruments**	**Microsurge Laser Fiber Holder**	**United States Surgical Corporation Endoscopic Needle Driver**	**Comparison**
					Otherwise function is the same. These differences do not introduce new concerns regarding safety and performance.
Shaft rotation	360°	360°	NA	360°	Same
How Supplied	Sterile single use only	Sterile single use only	Sterile single use only	Sterile single use only	Same
Tissue Contact Materials	Stainless steel, polymers, tungsten brazing, adhesives, lubricant, pad printing ink	Generally: Stainless steel, polymers, adhesives, pad printing ink	Generally: Stainless steel, polymers, adhesives, pad printing ink	Generally: Stainless steel, polymers, adhesives, pad printing ink	Similar, though differences may exists. All tissue contact materials in the Flex™ Instruments were evaluated for biocompatibility
Biocompatibility	Tissue contact materials are biocompatible per ISO 10993	Tissue contact materials are biocompatible per ISO 10993	Tissue contact materials are biocompatible per ISO 10993	Tissue contact materials are biocompatible per ISO 10993	Same
Electrosurgical safety	Complies with IEC requirements for electrical safety and electromagnetic compatibility	Complies with IEC requirements for electrical safety and electromagnetic compatibility	NA	NA	Same
Generator compatibility (where applicable)	Monopolar generator e.g. Covidien ForceTriad™ Energy Platform or	Monopolar generator e.g. Covidien ForceTriad™ Energy Platform or	NA	NA	Same

Substantial Equivalence Comparison Chart					
Feature/ Specification	**Flex™ Instruments**	**Covidien SILS and Endoscopic Instruments**	**Microsurge Laser Fiber Holder**	**United States Surgical Corporation Endoscopic Needle Driver**	**Comparison**
	equivalent	equivalent			
Warnings, cautions, and contraindications	Stated in IFU	Stated in IFU	Stated in IFU	Stated in IFU	Statements are similar for both the subject and predicate devices
Provided packaged sterile, single use only	Yes	Yes	Unknown	Unknown	Same
Sterilization	Gamma	Ethylene Oxide	Unknown	Unknown	Same
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	10^{-6}	Same

The differences between the subject device and the predicate device include minor differences in dimensional characteristics and functional characteristics such as the degree of articulation, length and diameters. The Flex™ Instrument product offering includes a needle driver and a laser fiber holder. These are non-active devices and have similar device features as the rest of the product offering and fall under the general category of endoscopic surgical instruments. Predicate devices have been identified for each. Testing conducted on the Flex™ Instruments demonstrate the safety and performance of these devices for their intended use, further supporting that the differences noted compared to the predicate do not raise new questions of safety and efficacy. The Flex™ Endoscopic Instruments are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 11, 2014

Design Standards Corporation
Ms. Michele Lucey
957 Claremont Road
Charlestown, New Hampshire 03603

Re: K140662
Trade/Device Name: Device Name: Flex™ Endoscopic Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, GEI, GEX
Dated: March 13, 2014
Received: March 19, 2014

Dear Ms. Lucey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140662

Device Name

Device Name: Flex™ Endoscopic Instruments

Indications for Use *(Describe)*

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The Flex™ Monopolar Scissor is a single use electrosurgical device intended to be used in conjunction with an electrosurgical generator with applications in endoscopic surgical procedures to facilitate cutting of tissue.

The Flex™ Laser Fiber Holder is a single use endoscopic device with applications in endoscopic surgical procedures to house and introduce a laser fiber.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

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